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In the Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, PETITIONER

v.

KATHLEEN E. LES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether a pesticide residue regulated as a food additive that poses only a de minimis risk of cancer is "unsafe" within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 348(c)(3)(A).

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OPINION BELOW

The opinion of the court of appeals, Pet. App. 1a-11a, is reported at 968 F.2d 985.

JURISDICTION

The judgment of the court of appeals was entered on July 8, 1992. A petition for rehearing was denied on September 25, 1992. The petition for a writ of certiorari was filed on November 6, 1992. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

This case involves efforts by the United States Environmental Protection Agency (EPA) to apply certain provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) in the context of pesticide residues on processed foods. In particular, under Section 402 of the FDCA, 21 U.S.C. 342, foods that contain unsafe food additives are deemed to be adulterated. A food additive is considered unsafe unless there is a specific regulation issued under Section 409 of the FDCA, 21 U.S.C. 348, describing the conditions under which the food additive may be considered safe. The so-called "Delaney Clause" in Section 409 (c) (3) (A) provides that "no [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." 21 U.S.C. 348(c) (3) (A).

1. The EPA regulates pesticides under two different statutes and three different legal standards. The most comprehensive of these statutes is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136-136y, which prescribes a licensing or registration system for pesticides sold or distributed in the United States. The standard for granting, cancelling, or suspending a pesticide registration is whether the pesticide poses "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb); see *Love* v. *Thomas*, 858 F.2d 1347, 1350 (9th Cir. 1988), cert. denied, 490 U.S. 1035 (1989).

The EPA also regulates pesticide residues in food under two separate provisions in the FDCA. Section 408 of the FDCA, 21 U.S.C. 346a, addresses pesticide residues in raw agricultural commodities. Under Sec-

tion 402(a)(2)(B) of the FDCA, 21 U.S.C. 342 (a)(2)(B), a raw agricultural commodity containing a pesticide residue is deemed adulterated unless that residue is authorized by a tolerance regulation or exemption from tolerance established under Section 408. To establish a tolerance regulation or exemption from a tolerance under Section 408, the EPA must find that the regulation will "protect the public health." 21 U.S.C. 346a(b). In reaching this determination, the EPA is required to consider the "necessity for the production of an adequate, wholesome, and economical food supply." 21 U.S.C. 346a(b). The EPA also regulates certain pesticide residues in some processed foods under Section 409 of the FDCA, 21 U.S.C. 348. Like Section 408, Section 409 establishes a scheme whereby processed foods containing a food additive are deemed adulterated unless the food additive has been authorized by a regulation. The EPA has interpreted the term "food additive" as applying to those pesticide residues in processed foods which exceed the tolerance for the relevant raw agricultural commodity. 40 C.F.R. 177.1(c). The establishment of a food additive regulation under Section 409 requires a finding under the "general safety clause" in Section 409(c)(3) that the use of a pesticide "will be safe." The general safety clause, in turn, is modified by the Delaney Clause.[1]

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[1] Only certain pesticide residues are regulated under Section 409 (and subject to the Delaney Clause) because of the "flow-through" provision in Section 402(a)(2)(C) of the FDCA, 21 U.S.C. 342(a)(2)(C). That provision establishes that Section 408 raw food tolerances "flow through" to cover pesticide residues in processed foods resulting from application of the pesticide to the raw food. Thus, if the concentration of the pesticide residue in the processed food does not exceed the

2. On February 25, 1991, the EPA issued a final order denying in part an administrative petition that had sought the revocation of several regulations issued under Section 409(c)(3)(A) of the FDCA, 21 U.S.C. 348(c)(3)(A). 56 Fed. Reg. 7750 (1991). The regulations covered certain pesticide residues in processed foods where the residues were found to be carcinogenic after the regulations had been originally established. The EPA denied the petition based on its conclusion that the Delaney Clause allowed the agency to adopt a de minimis exception for pesticide uses that posed a trivial risk of causing cancer. The EPA found that several of the pesticides posed only trivial risks of causing cancer and therefore declined to revoke the regulations permitting such residues on processed foods.[2]

3. Respondent Kathleen E. Les, among others,[3] sought review in the court of appeals of the EPA's final order, and the court of appeals reversed the EPA's decision. Pet. App. 1a-11a. According to that court, "the language of the Delaney clause, its history and purpose all reflect that Congress intended the EPA to prohibit all additives that are carcino-

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tolerance set for the raw agricultural commodity under Section 408, the residues may legally be present in the processed food without the need for setting and satisfying a separate tolerance under Section 409.

[2] The food additive regulations at issue set tolerances for 14 uses for seven separate pesticides. The lifetime risk of contracting cancer posed by the uses challenged by the respondents in the court of appeals was, at most, between approximately 1×10^{-7} and 2×10^{-11} (or approximately one in 10,000,000 and two in 100,000,000,000).

[3] We will hereafter use the term "respondents" to refer only to the non-federal respondents.

gens, regardless of the degree of risk involved." *Id.* at 2a-3a. The EPA therefore could not adopt a de minimis interpretation of that Clause. The court also ruled that the Delaney Clause unambiguously applies to the pesticide residues at issue in this case. *Id.* at 8a, 10a.

ARGUMENT

Although we disagree with the court of appeals' decision, we do not believe that the case warrants review by this Court.

1. There is no conflict among the circuits on the question presented in the petition; in fact, no other court of appeals has addressed that precise issue.[4] Moreover, the decision below is consistent with the D.C. Circuit's decision in *Public Citizen* v. *Young*, 831 F.2d 1108 (1987), cert. denied, 485 U.S. 1006 (1988), which held that a color additive that poses only a de minimis risk of cancer is "unsafe" within the meaning of the Color Additive Amendments of 1960 to the FDCA, 21 U.S.C. 376(b)(5)(B)(ii).[5]

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[4] The decision below also does not conflict with the Ninth Circuit's earlier decision in *Love* v. *Thomas*, 858 F.2d 1347 (1988), cert. denied, 490 U.S. 1035 (1989). That case involved review of an EPA decision under FIFRA, which requires the EPA to consider cost factors in registering or cancelling pesticide uses. The court held that the EPA's consideration of those factors in that particular case was inadequate. 858 F.2d at 1357-1363. *Love* addressed only the FIFRA question and did not involve the FDCA or the Delaney Clause. Nor did that case hold that the FIFRA cost-benefit standard overrides the zero-risk standard in the Delaney Clause. In any event, an alleged intracircuit conflict is for the court of appeals, not this Court, to resolve. *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957).

[5] The court in *Public Citizen* reserved comment on the question in this case, since that question did not arise there. 831 F.2d at 1118 n.13, 1120.

Petitioners argue that the decision below is inconsistent with *Public Citizen*, because, they maintain, the court of appeals failed to justify its holding in light of the apparently conflicting provisions of FIFRA and the FDCA. Pet. 18-22. That claim lacks merit.

In *Public Citizen*, a unanimous panel of the D.C. Circuit rejected the Food and Drug Administration's view that the Delaney Clause in Section 706 of the FDCA allowed the agency to adopt a de minimis exception to the otherwise flat ban in that provision. In so ruling, the D.C. Circuit pointed to three factors in determining whether a de minimis interpretation was appropriate: (1) whether the risk is negligible or trivial; (2) whether Congress had been extraordinarily rigid in its legislation, thereby evincing an intent to foreclose a de minimis exception; and (3) whether de minimis authority would further the legislative design or frustrate congressional intent. 831 F.2d at 1112-1113. The court concluded that the text and legislative history of the Color Additives Amendment precluded the FDA from adopting a de minimis exception to the Delaney Clause, because Congress had been extraordinarily rigid concerning the need for an anti-cancer clause, had carefully considered the need for the Delaney Clause, had exhaustively reviewed alternatives, and only then had emphatically rejected the alternatives. *Id.* at 1113-1115. Also, the court found that application of a strict standard was consistent with the safety goals of the legislation, given the relatively low societal value Congress placed on color additives. *Id.* at 1117-1118. Here, the court of appeals considered the EPA's argument that a de minimis exception helped resolve apparently conflicting congressional directives. Pet.

App. 7a, 10a. The court below therefore conducted the type of analysis that the D.C. Circuit set forth in *Public Citizen*.

Petitioner also argues that the court of appeals' decision "conflicts with the *de minimis* principle," Pet. 15, as recently articulated in *Wisconsin Dep't of Revenue* v. *William Wrigley, Jr., Co.*, 112 S. Ct. 2447 (1992). In that case, this Court stated that the principle of *de minimis non curat lex* is a "venerable maxim" of statutory construction and can be applied in matters of statutory interpretation "absent contrary indication." *Id.* at 2457-2458. In this case, the court of appeals found that the text, legislative history, and purposes of the Delaney Clause supply precisely the "contrary indication" necessary to preclude application of the de minimis principle. The decision below therefore does not conflict with the de minimis principle discussed in the *Wrigley* case.

2. Petitioner contends that the court of appeals failed to afford EPA appropriate deference in reviewing the agency's interpretation of the Delaney Clause. Pet. 22-26. That claim does not warrant further review.

It is well-settled that when a court reviews an administrative construction of a statute that an agency is responsible for administering, the court must determine whether Congress has resolved the particular question at issue. If Congress has done so, its resolution is binding on the agency and the courts. *Chevron U.S.A. Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 842-843 (1984). By contrast, if a reviewing court cannot find a clearly discernible congressional intent, "the court does not simply impose its own construction on the statute." *Id.* at 843. Instead, the court must determine whether the agency's construction is per-

missible or is "arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 844.

In this case, the court of appeals followed the analysis set forth in *Chevron*. It determined that Congress's intent regarding the meaning and effect of the Delaney Clause was clear and unambiguous. Pet. App. 3a-4a. The court cited evidence in the statutory text and legislative history as indicating that Congress intended the Delaney Clause to operate in a rigid fashion and that this rigid standard applied to the concentrating pesticides at issue in this case. Having reached that conclusion, it would not have been appropriate under *Chevron* for the court of appeals to have given deference to the agency's interpretation.

3. The adverse effects identified by petitioners may stem in part from EPA's policies and regulations regarding the coordination of its authority under Section 409 with its authority under Section 408 and FIFRA, rather than being the inevitable consequence of the Ninth Circuit's interpretation of the Delaney Clause.[6] Once this litigation is final, EPA will review its regulations and policies regarding the interrelation of its authorities concerning pesticides. EPA will determine whether changes in its policies and

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[6] For example, EPA has traditionally refused to register a pesticide use under FIFRA or approve a Section 408 raw food tolerance if EPA determines that there is a possibility that residues in a processed food could exceed the raw food tolerance and a Section 409 food additive regulation could not be approved. In the wake of the Ninth Circuit's decision in this case, various food processor and food growing groups have petitioned EPA to rescind that policy claiming it is both illegal and unsound. EPA is currently considering that petition.

regulations are legally permitted or possibly required, and, if EPA's authority is found to be permissive, whether any change is a rational policy choice. A change in EPA's policy may ameliorate many of the adverse consequences feared by petitioners. To be sure, changes in EPA's policy on coordinating its authorities over pesticides would represent a major alteration of the existing pesticide regulatory scheme as administered by EPA for the last 20 years. Such changes could have substantial impacts on consumers, growers, the pesticide industry, and EPA, and EPA will need to assess the extent of these effects in considering any policy changes. Nevertheless, due to the uncertainty regarding the type of effects that will result from the Ninth Circuit's decision, there is no need to grant discretionary review at this time.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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